PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	03 OCT 2005
Applicant's or agent's file reference P-6867-PC	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL04/00532	17 June 2004 (17.06.2004)	20 June 2003 (20.06.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A23C 9/20 and US Cl.: 426/585

Applicant

NUTRINIA LTD

1. This opinion contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis(b)* that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571)273-8300	Authorized officer Pili A. Hawes Telephone No. 571-272-1600

Form PCT/ISA/237 (cover sheet) (January 2004)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL04/00532

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL04/00532

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 12-15, 17-19, 51-52, 56, 71	YES
	Claims 1-11, 16, 20-50, 53-55, 57-70, 72-87	NO
Inventive step (IS)	Claims NONE	YES
	Claims 1-87	NO
Industrial applicability (IA)	Claims 1-87	YES
	Claims NONE	NO

2. Citations and explanations:

Please See Continuation Sheet

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:
Claims 1-11, 16, 20-50, 53-55, 57-70, 72-87 lack novelty under PCT Article 33(2) as being anticipated by RUBIN US 5013569.

RUBIN teaches a method of encapsulating bioactive materials such as immunoglobulins and omega-3 fatty acids and fortifying infant formula with the composition. Various methods for micro encapsulation are disclosed, such as forming micelles in water-in-oil emulsions, spray drying to make fine particles, decreasing the solubility of a polymeric solution to induce coacervation, modifying the temperature of a polymeric solution until the polymer is no longer soluble and precipitates, interfacial polymerization, or the capsules can be formed in a dry blending process using free-flowable inclusion compounds such as cyclodextrins. This anticipates the "grinding a dry blend" limitation because inorder for a powder mixture to be free flowable it must be ground to make them fine particles. The particles disclosed, sizes 80-300 nm, or 250 microns, resulting from the methods of encapsulation disclosed, anticipate instant claims to the particle sizes of the microcapsules. RUBIN further teaches the infant formulation can be in the form of a concentrated powder or liquid, or in a ready to use form. RUBIN teaches the inclusion of feed or food grade materials in the composition such edible fats, non-fat milk, peanut oil, soybean oil, whey, sugars, vitamins and minerals. RUBIN discloses that acid milk whey contains beta lactoglobulins, immunoglobulins, and serum albumin. The formulation of the infant formula is intended to mimic human mother's milk. Humans are primates, this teaching therefore anticipates instant claims. The method also includes administering the formula composition to premature infants. Human milk is beneficial to human infants and a composition with added immunoglobulins will help boost the infants immunity, which would improve the health status of an infant. Therefore the instant claims are anticipated.

Claims 1-87 lack an inventive step under PCT Article 33(3) as being obvious over RUBIN US 5013569 in view of PAUL US 5531989. The limitations taught by RUBIN are discussed above.

PAUL teaches the same ingredients for the production of a concentrate that contains milk protein, immunoglobulins, fiber, and other feed/food grade materials. PAUL teaches the use of carbohydrates such as maltodextrin in the composition, and the source of the immunoglobulin from milk products and whey. The immunoglobulin concentrate is formed by freeze-drying or spray drying methods. Paul teaches the composition can be reconstituted in water or other liquids. PAUL teaches in the incorporation of other bioactive compounds such as insulin in the composition.

It would be obvious to one of ordinary skill to incorporate the maltodextrin taught by PAUL in the microencapsulating process taught by RUBIN because PAUL teaches the same ingredients as RUBIN and also teaches a concentrate formulation. It would also be obvious to use freeze-drying and spray drying techniques in formation of the product because both RUBIN and PAUL teach this process.

Claims 1-87 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of JANDA et al. US 5418010.

JANDA further teaches that spray drying and extrusion are processes widely used by those of ordinary skill in the art for microencapsulating processes.

It would be obvious to one of ordinary skill in the art to employ these methods in forming microencapsulated particles for incorporation in infant formula because JANDA teaches that these processes are well known in the art. Also RUBIN discloses a variety of methods are

Supplemental Box
In case **the space in any of the preceding boxes is not sufficient.**

possible for the preparation of microencapsulated particles.

Claims 12-15, 17-19, 51-52, 56, 71 meet the criteria set out in PCT Article 33(2), because the prior art does not teach the exact limitations as set forth in the instant claims.

Claims 1-87 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.